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09/887,880	06/22/2001	Jason Francis Conaty	65340/JPW/GJG	4388

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EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

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10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/887,880

Applicant(s)

CONATY ET AL.

Examiner

Janet L Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 25-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-10,15-24 and 32-34 is/are rejected.
- 7) ☒ Claim(s) 3,6 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-24 and 32-34 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examiner has not addressed how to treat withdrawn process claims once the product claim is allowed. This is not found persuasive because Applicants have based their arguments upon the alleged allowability of the product claims, it is improper for Applicants to assume initially that the product claims are allowable and therefore the process claims must be rejoined. Applicant's arguments are presumptuous; the restriction of the process claims, as set forth in the initial restriction requirement is considered appropriate because "[F]or purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02." As stated in the prior Office action the product claims are classifiable in 435/91.31, and the process claims are classifiable in 514/44.

Additionally, in regards to the restriction of Groups I and II, applicants point out that claim 1 is a linking claim that links the inventions of Group I and II, and that claim 1 should be examined for both structures 1A and 1B, once applicants' elected invention is found allowable. Again, Applicant's arguments are based upon the presumption that claim 1 is allowable. However, as set forth below, claim 1 is rejectable over the prior art as set forth below.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 25-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 9.

3. Claims 12-14 are drawn to the compound of claim 1, wherein said compound has the structure according to 1b, wherein such compounds are drawn to structure 1b, these compounds are withdrawn from considerations as being drawn to a non-elected invention in Paper No. 9.

4. Claims 1-11, 15-24, and 32-34, will be examined to the extent that these claims are drawn to a compound of formula 1A, and compositions thereof.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-10, 24, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the compound of claim 5, wherein the linker sequence is a sequence of the class WYHH," there is insufficient antecedent basis for this limitation in the claim.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

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raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 24 recites the broad recitation mammalian host cell, and the claim also recites monkey COS and hamster ovary host cells, which are narrower statements of the range/limitation.

Claims 32-34 recite the phrase "capable of hybridizing with." This phrase is vague and indefinite since applicants have not defined the conditions of hybridization wherein the compounds of the present invention are capable of hybridizing to a target sequence.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4-5, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Biochemical and Biophysical Research Communications (1998), 250(3), 711-719).

Wang et al. disclose the hammerhead ribozyme sequence according to 5'-AAA-CUU-CGA-GAC-GAC-UGA-UGA-GGC-GCU-CGA-AAG-3' (see page 714, Hrbz, X2=A and X1=G). This sequence corresponds to the sequence wherein: (X)<sub>n</sub>' is AAA-CUU-CGA-GAC-GA, X' is "U," (X)<sub>a</sub> is G, NNHH is CGCU, and (X)<sub>n</sub> is AG. The ribozyme structure of Wang et al.

*X<sub>a</sub> - is missing*

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meets the structural limitations of the formula according to structure 1A of claim 1. Additionally, the 3'-(X)<sub>n</sub>1 nucleotide of Wang et al. is "A." Additionally, n+n' is greater than 14.

Wang et al. also disclose the following compound: 5'-A-A-A-C-U-U-C-G-A-G-A-C-G-A-C-U-G-A-U-G-A-G-G-C(oxyphosphinicooxy-1,3-propanediyl oxyphosphinicooxy)C-U-C-G-A-A-G-G-3' (see page 714, Hrbz, X<sub>2</sub>=A and X<sub>1</sub>= non-nucleotide linker), this sequence is encompassed by the compound according to structure 1A wherein (X)<sub>a</sub> is absent, and furthermore wherein the linker sequence 5'-NNHH-3' and 5'-DYHH-3' has a sequence according to 5'-GCCU-3'. It is noted that the (X)<sub>n</sub> regions function in an antisense manner and therefore these regions can be considered antisense oligonucleotide structures.

Wang et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

10. Claims 1-2, and 15-24 are rejected under 35 USC 102(b) as being anticipated by Akhtar et al.

Akhtar et al. disclose a ribozyme comprising the following sequence: 5'-G-U-C-C-U-G-G-G-C-U-G-A-U-G-A-N-G-A-A-A-U-C-G-A-A-A-G-3' (see Table III, SEQ ID NO: 1274). This ribozyme comprises a sequence encompassed by structure 1A as recited in claim 1 of the instant application. Wherein (X)<sub>n</sub>' is G-U-C-C-U-G-G-G, X' is U, (X)<sub>a</sub> is N, NNHH is AAAU, and (X)<sub>n</sub> is AG.

Akhtar et al. also disclose ribozymes complexed with cationic lipids, packaged within liposomes for delivery to target cells (page 9, lines 31-34). These ribozymes may also be expressed from transcription units inserted into DNA or RNA vectors, preferably DNA plasmids or viral vectors (see page 11, lines 11-30). The ribozyme encoding sequences incorporated into a

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DNA or RNA expression vector may be driven by promoter sequences from RNA polymerase I, II or polymerase III, in addition prokaryotic RNA polymerase promoters may also be used. These ribozyme transcription units may be expressed in prokaryotic cells and mammalian cells. (see all of page 22).

Akhtar et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

11. Claims 1-2 are rejected under 35 USC 102(b) as being anticipated by Zwick et al.

Zwick et al. disclose a ribozyme having the following formula: 5'-GGCUGAUGCUGA-UGANGAAAACGAAAA-3' (see Table V, page 52, ribozyme targeting position #10). This ribozyme comprises a sequence encompassed by structure 1A as recited in claim 1 of the instant application, specifically wherein the 5'-NNHH-3' sequence is 5'-AAAA-3'.

Zwick et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

### *Conclusion*

12. Claims 3, 6 are 11 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 7-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. The prior art does not teach nor suggest the compounds according to structure 1A wherein the 5'-NNHH-3' sequence has a sequence according to GUAA, GAUA, CGUU, UGUU,

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UAAC, or WYHH. Additionally, there does not appear to be any motivation in the prior art to modify the ribozyme sequences disclosed by any of the cited references to comprise these sequences.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.  
Examiner  
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*JLE*  
December 30, 2002

  
**SEAN MCGARRY**  
**PRIMARY EXAMINER**